UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

JOHN AUSTIN,

Plaintiff,

v.

BOEHRINGER INGELHEIM PHARMACEUTICAL INC.,

Defendant.

Case No. 3:21-cv-10069-JD

ORDER RE MOTION TO DISMISS

This case involves a prescription anticoagulant medication, Pradaxa (dabigatran). Pro se plaintiff John Austin's wife, Lisa Austin, was prescribed Pradaxa, took it, and later developed interstitial lung disease and died. Dkt. No. 42 at 2. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI) is "responsible for the drug [Pradaxa] in the United States." Dkt. No. 46 at 1. Austin alleges that BIPI's label for Pradaxa "does not warn of the association with" interstitial lung disease, and that BIPI "was obligated to give such warning under FDA rules and California law." Dkt. No. 42 at 3. BIPI asks to dismiss Austin's second amended complaint (SAC). Dkt. No. 46. The parties' familiarity with the record is assumed, and dismissal is denied.

LEGAL STANDARDS

The standards for a motion to dismiss under Rule 12(b)(6) are well-established. The Court's prior statements of the standards are incorporated here. *See Duque v. Permanente Med. Grp.*, No. 18-cv-03356-JD, 2019 WL 13254072, at *2 (N.D. Cal. July 1, 2019); *Hostetler v. Wormuth*, No. 22-cv-03605-JD, 2023 WL 2959994, at *1 (N.D. Cal. Apr. 14, 2023). In pertinent part, a claim must provide "a short and plain statement . . . showing that the pleader is entitled to relief," Fed. R. Civ. P. 8(a)(2), including "enough facts to state a claim . . . that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). A claim is plausible on its face if,

accepting all the factual allegations as true and construing them in the light most favorable to the plaintiff, the Court can reasonably infer that the defendant is liable for the misconduct alleged. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). The Court will not treat as fact or accept as true allegations that are bare legal conclusions, recitations of elements, or unwarranted deductions. *See id.*; *see also In re Gilead Scis. Sec. Litig.*, 536 F.3d 1049, 1055 (9th Cir. 2008). The plausibility analysis is "context-specific" and not only invites but "requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 679. The Court has a "duty 'to construe pro se pleadings liberally, including pro se motions as well as complaints.'" *Choudhuri v. Specialized Loan Servicing*, No. 19-cv-04198-JD, 2019 WL 3323088, at *1 (N.D. Cal. July 24, 2019) (quoting *Bernhardt v. Los Angeles Cnty.*, 339 F.3d 920, 925 (9th Cir. 2003)).

DISCUSSION

I. TIMELINESS

BIPI suggests that Austin's claims are barred by California's two-year statute of limitations for personal injury and wrongful death actions. Dkt. No. 46 at 3-4 (citing Cal. Code Civ. Proc. § 335.1). BIPI says that (1) Austin's claims accrued on November 2, 2018, the day his wife passed away; (2) Austin filed his original complaint in state court on November 2, 2020, but named Boehringer Ingelheim Corporation (BIC) as a defendant and not BIPI; (3) BIPI was named as a defendant in the first amended complaint that was filed on May 23, 2022, but it was never served with that complaint; and (4) BIPI was served with the SAC on January 23, 2023, "over four years after [Austin's] claims accrued." *Id.* at 4. BIPI contends that Austin's claims against it cannot be related back to the filing of his original complaint because no defendant was served with that complaint within the 90-day period contemplated by Federal Rule of Civil Procedure 4(m). *See* Fed. R. Civ. P. 15(c)(1)(C) ("An amendment to a pleading relates back to the date of the original pleading when . . . the amendment changes the party or the naming of the party against whom a claim is asserted, if . . . within the period provided by Rule 4(m) for serving the summons and complaint, the party to be brought in by amendment . . . received such notice of the action that it will not be prejudiced in defending on the merits . . . .").

The point is not well taken. It is true that the "title of the complaint must name all the parties." Fed. R. Civ. P. 10(a). But the caption of the complaint is not necessarily determinative as to the identity of the parties. *See United States ex rel. Eisenstein v. City of New York*, 556 U.S. 928, 935 (2009) (citing 5A C. Wright & A. Miller, Federal Practice and Procedure § 1321, p. 388 (3d ed. 2004) ("[T]he caption is not determinative as to the identity of the parties to the action."). And Rule 8(e) requires that "[p]leadings must be construed so as to do justice." Fed. R. Civ. P. 8(e). In this case, the caption of Austin's original complaint listed "Boehringer Ingelheim, a corporation" as a defendant. Dkt. No. 1-5 at ECF p. 3. The second paragraph of the complaint explicitly refers to "Defendant Boehringer Ingelheim Pharmaceuticals, Inc.," *id.* at ECF p. 4, and nowhere does the complaint mention BIC. In moving to dismiss the original complaint, BIC recognized that Austin "directed his allegations to BIPI." Dkt. No. 7 at 1. BIPI says that only BIC was served with the complaint, but the record is unclear about the circumstances surrounding service.[1] Under these circumstances, and given that BIPI, which is represented here by the same counsel as BIC, will experience little if any prejudice, the Court declines to dismiss Austin's suit on timeliness grounds.

II. DUTY TO WARN

BIPI says that it had no duty to warn of an association between Pradaxa use and interstitial lung disease. *See* Dkt. No. 46 at 8. "Under California law, drug manufacturers have a duty to warn physicians of risks that are known or scientifically knowable at the time of the drug's distribution." *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1238 (9th Cir. 2017). "The manufacturer has no duty to warn of risks that are 'merely speculative or conjectural, or so remote and insignificant as to be negligible.'" *T.H. v. Novartis Pharmaceuticals Corp.*, 4 Cal. 5th 145, 164 (2017) (quoting *Carlin v. Superior Court*, 13 Cal. 4th 1104, 1116 (1996)). "If the

[1] "Boehringer Ingelheim" is the name of the party that was served, according to the records of the San Francisco Superior Court. *See* Proof of Service as to Defendant Boehringer Ingelheim, a Corporation, filed in *Austin v. Boehringer Ingelheim*, No. CGC-20-587448 (S.F. Super. Ct. Dec. 7, 2021); *see also Friends of Gualala River v. Gualala Redwood Timber, LLC*, 552 F. Supp. 3d 924, 930 n.2 (N.D. Cal. 2021) ("The Court may take judicial notice of . . . state court documents.").

manufacturer provides an adequate warning to the prescribing physician, the manufacturer need not communicate a warning directly to the patient who uses the drug." *Id.*

The complaint plausibly alleges that BIPI had a duty to warn. Austin says that BIPI "knew or should have known that their product was associated with and or a causal factor in [interstitial lung disease] and they failed to warn consumers and medical personal [*sic*] of that information." Dkt. No. 42 at 3. Austin cites and attaches a case report that notes that in 2011, "the Ministry of Health, Labour and Welfare of Japan issued an alert that dabigatran administration might be associated with interstitial lung diseases, including death in cases with preexisting interstitial pneumonia." *Id.* at ECF p. 7. The report discusses a case where a "patient's interstitial pneumonia was diagnosed to be a drug-induced lung injury caused by dabigatran." *Id.* at ECF p. 5. BIPI objects that the case report "cannot plausibly create the foundation for a lawsuit alleging that BIPI had an affirmative duty to warn of the hypothetical risk," but relies principally on cases that were decided at summary judgment, on more developed factual records. Dkt. No. 46 at 8-9 (citing, for example, *Wendell v. SmithKline Beecham*, No. 09-cv-04124-CW, 2018 WL 6267855, at *5 (N.D. Cal. Aug. 15, 2018); *Salinas v. City of San Jose*, No. 09-cv-04410-EJD, 2013 WL 2450114, at *6 (N.D. Cal. June 5, 2013)). At this early pleadings stage, the allegations are enough to go forward with an eye towards revisiting the question on a fully developed record.

III. FEDERAL PREEMPTION

BIPI says that Austin's failure-to-warn claim is impliedly preempted by federal law. *See* Dkt. No. 46 at 10. "Even in the absence of an express pre-emption provision, the [Supreme] Court has found state law to be impliedly pre-empted where it is 'impossible for a private party to comply with both state and federal requirements.'" *Mut. Pharm. Co., Inc. v. Bartlett*, 570 U.S. 472, 480 (2013) (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)). "The question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it." *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 620 (2011). This form of federal preemption, known as impossibility preemption, "is a demanding defense." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009).

The Food and Drug Administration (FDA), acting pursuant to its authority under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* (FDCA), "regulates the safety information that appears on the labels of prescription drugs that are marketed in the United States." *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672 (2019). "FDA regulations set out requirements for the content, the format, and the order of the safety information on the drug label." *Id.* at 1673. "Prospective drug manufacturers work with the FDA to develop an appropriate label when they apply for FDA approval of a new drug." *Id.* "But FDA regulations also acknowledge that information about drug safety may change over time, and that new information may require changes to the drug label." *Id.* (citing 21 C.F.R. §§ 314.80(c), 314.81(b)(2)(i)). "Drug manufacturers generally seek advance permission from the FDA to make substantive changes to their drug labels." *Id.* "However, an FDA regulation called the 'changes being effected' or 'CBE' regulation permits drug manufacturers to change a label without prior FDA approval if the change is designed to 'add or strengthen a . . . warning' where there is 'newly acquired information' about the 'evidence of a causal association' between the drug and a risk of harm." *Id.* (quoting 21 C.F.R. § 314.70(c)(6)(iii)(A)). FDA regulations provide that "the labeling must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitively established." 21 C.F.R. § 201.57(c)(6)(i).

The CBE regulation allows brand-name manufacturers to provide the warnings required by state law before receiving FDA approval, which can undercut an impossibility preemption defense. *See Levine*, 555 U.S. at 571. But "the FDA retains authority to reject labeling changes made pursuant to the CBE regulation." *Id.* Consequently, the Supreme Court has held that "state law failure-to-warn claims are pre-empted by the [FDCA] and related labeling regulations when there is 'clear evidence' that the FDA would not have approved the warning that state law requires." *Albrecht*, 139 S. Ct. at 1676 (quoting *Levine*, 555 U.S. at 571).

The application of these principles here is subject to the additional consideration of the pleadings motion at hand. Federal preemption is an affirmative defense. "An affirmative defense is grounds for dismissal at the pleading stage only if 'the plaintiff pleads itself out of court -- that

is, admits all the ingredients of an impenetrable defense.'" *Boquist v. Courtney*, 32 F.4th 764, 774 (9th Cir. 2022) (quoting *Durnford v. MusclePharm Corp.*, 907 F.3d 595, 603 n.8 (9th Cir. 2018)).

BIPI suggests that Austin "must plead a labeling deficiency that [it] could have corrected using the CBE regulation," Dkt. No. 46 at 10 (internal quotations, citation, and emphasis omitted), and faults Austin for not coming forward with sufficient evidence of a causal association between Pradaxa and interstitial lung disease, *see* Dkt. No. 49 at 5-6. A handful of other circuits appear to have adopted the threshold pleading requirement that BIPI proposes. *See, e.g.*, *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 708 (2d Cir. 2019) ("[T]o state a claim for failure-to-warn [based on post-drug-release information] that is not preempted by the FDCA, a plaintiff must plead a labeling deficiency that [the defendant] could have corrected using the CBE regulation.") (internal quotations and citation omitted).

BIPI's preemption argument raises factual issues that are better suited for resolution on a fully developed record. It is declined for that reason under Rule 12(b)(6). It also bears mention that the Ninth Circuit has not adopted the approach taken by other courts, and a good argument can be made that such an approach cannot be readily reconciled with our rules on the treatment of affirmative defenses at the motion to dismiss stage.

CONCLUSION

BIPI's motion to dismiss is denied. The parties are directed to meet and confer on a proposed amended scheduling order that allows adequate time for discovery and trial preparation. They are directed to jointly file their proposed schedule by June 2, 2023.

Austin may wish to consult with the District's Legal Help Center. Lawyers at the Center can provide basic assistance to parties representing themselves, but not legal representation. Appointments can be made by calling (415) 782-8982 or emailing fedpro@sfbar.org.

IT IS SO ORDERED.

Dated: May 12, 2023

JAMES DONATO
United States District Judge